REMARKS

I. Claim Objections

The Examiner has objected to claim 108 stating that in the absence of a preamble it is unclear whether step (3) achieves the desired result and whether claim 108 is the complete claimed method.

Applicants note that the preambles of claims 108, 125 and 142 have been restored.

II. Rejections Under 35 USC §103 – Obviousness

The Examiner has rejected claims 108-113, 115-130 and 132-146 as being unpatentable over Maeda *et al.*, in view of Prud'homme *et al.*, and Scott *et al.* The Examiner states that Maeda *et al.* disclose the nucleotide and amino acid sequences of a feline herpesvirus type I (FHV I) glycoprotein C (gC) protein that differs from the instantly claimed SEQ ID NO:18 and 20 by a single amino acid, which, lacking evidence to the contrary, is *de minimis*. The Examiner further states that Maeda et al. disclose that the gC protein is one of the most important subunit antigens in vaccine immunity for FHV-1 infection of cats, and that mAbs reacting to gC can be used to evaluate antigen in vaccines. The Examiner states that while Maeda *et al.* do not disclose the detection of antibody:protein complexes prior to vaccination, Prud'homme *et al.* teach an ELISA that uses recombinant herpesvirus glycoprotein gp50 to detect antibodies to the pseudorabies virus (PRV) (an alphaherpesvirus) in animal sera. Finally, the Examiner states that while Prud'homme *et al.* do not suggest vaccination in the absence of an antibody:protein complex, Scott *et al.* disclose a method of evaluating the duration of immunity in cats vaccinated against FHV, FPV and FCV, and also specifically recommend that cats be revaccinated against these viruses. The Examiner concludes it would have been obvious to modify and use the gC protein of Maeda *et al.* to detect antibody:protein complexes, as taught by Prud'homme *et al.*, and further, to use the results of such an assay to decide whether to vaccinate a cat against FPV-FHV-FCV as suggested by Scott *et al.* The Examiner further contends that one of skill in the art would have been motivated to make the suggested combination since Maeda *et al.* explicitly suggest the application of the FHV gC protein as an important subunit vaccine in immunity in cats.

First, Applicants contend that the combination of Scott *et al.* and Maeda *et al.* is improper since neither of these references provide a nexus between detecting protective antibodies in sera,

and the gC protein of FHV. Scott *et al.* teach determining the titer of anti-FHV antibody. To do so, Scott *et al.* employed virus neutralization (VN) assays that utilized whole virus, not recombinant antigen. Conscquently there is no way of knowing which, if any, particular viral protein was targeted by the neutralizing antibodies. In fact it is quite possible that neutralization resulted from the collective binding of several antibodies to the virus, each antibody recognizing a different viral protein. Therefore, nothing in the teaching of Scott *et al.* suggests that the neutralization of virus (i.e., protective effect) was due to a specific FHV protein, and in particular, the gC protein. Thus Scott *et al.* provide no motivation to detect anti-gC antibody, and thus fails to provide motivation to combine with the teaching of Maeda *et al.*

Next, while the Examiner interprets Maeda *et al.* as teaching that antibodies to the gC protein of FHV are the most important in immunity to infection, Applicants believe this interpretation of Maeda *et al.* is incorrect. What Maeda *et al.* actually teach, particularly at page 108, last paragraph (cited by the Examiner), is that their results "*might* contribute for the evaluation of the gC protein as one of the most important" antigens in immunity (emphasis added). It is Applicants' position that the phrase "might contribute for the "evaluation" is nothing more than a suggestion by Maeda *et al.* to further explore the role of the gC protein in immunity to infection. It is not teaching that antibodies to the gC protein are responsible for protection from infection.

Similarly, Applicants note that Maeda *et al.* use the phrase "*one of the* most important", as opposed to "the most important", when postulating which antigens might be involved in immunity to infection. Applicants contend that use of this phrase is an acknowledgement by Maeda *et al.* that viral proteins other than gC may be responsible for immunity to infection. In support of this contention, Applicants note that the statements of Maeda *et al.* are based on the work of Horimoto *et al.* (a copy of which is attached for the Examiner's convenience), who disclosed that anti-gC antibodies have virus neutralization activity. However, Horimoto *et al.* teach that "...three kinds of FHV-1 gps, with MW's of 60 kDa, 113 kDa and 143/108 kDa, are capable of eliciting neutralizing antibodies." (see page 131, 2nd and 3rd paragraph, of Horimoto *et al.*). Thus, the disclosure in Horimoto *et al.* that several FHV proteins can generate neutralizing antibodies dispels the idea that this ability is unique to the gC protein, and that, consequently, the gC protein must be key for protection from immunity. Furthermore, it should be noted that neither Maeda *et al.* nor Horimoto *et al.* disclose any correlation between the ability

of a protein to generate neutralizing antibodies in vitro, and the ability of that same protein to generate protective antibodies in an animal. In summary, it is Applicants' position that Maeda *et al.* fail to provide any teaching or evidence that the gC protein is responsible for protection from immunity, and thus the reference fails to provide any motivation to determine the titer of anti-gC antibodies in an animal.

Finally, Applicants note that at the time Scott *et al.* were designing assays to measure the duration of immunity, the teaching of Maeda *et al.* had already been available for several years. Applicants argue that if the disclosure of Maeda *et al.* made using the gC protein to detect protective antibodies obvious, Scott *et al.* would have designed their assay using recombinant gC protein. However, Scott *et al.* chose to use whole virus instead of the gC protein. Applicants contend that the choice by Scott *et al.* to use whole virus instead of gC protein is evidence that the teaching of the prior art did not render the use of gC protein in the detection of protective antibodies obvious.

In conclusion, Applicants reiterate their position that they were the first to show that antibodies to the gC protein of FHV could be used to determine immunity to infection by FHV, and thus the need to vaccinate the animal. Furthermore, Applicants believe that such a use was not obvious as stated in the arguments above, and therefore, Applicants request withdrawal of the obviousness rejection under 35 U.S.C §103(a).

CONCLUSION

All of the pending Claims are believed to be in condition for allowance. In the event the Examiner has any questions regarding this Application, the Examiner is invited to contact the undersigned representative at (970) 493-7272, ext. 4174.

Respectfully submitted,

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By: 

Richard J. Stern, Ph.D.
Registration No. 50,668
Heska Corporation
3760 Rocky Mountain Avenue
Loveland, Colorado 80538
Telephone: (970) 493-7272, 4174
Facsimile: (970) 619-3011